

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.,

Plaintiff,

v.

APOTEX, INC., LUPIN LIMITED,  
LAURUS LABS LIMITED, SHILPA  
MEDICARE LIMITED, SUNSHINE  
LAKE PHARMA CO., LTD., NATCO  
PHARMA LIMITED, CIPLA LIMITED,  
MACLEODS PHARMACEUTICALS  
LTD., HETERO USA INC., HETERO  
LABS LIMITED UNIT-V, AND HETERO  
LABS LIMITED,

Defendants.

C.A. No. 20-189 (MN)

REDACTED

**LETTER TO THE HONORABLE MARYELLEN NOREIKA  
REGARDING DISCOVERY DISPUTE**

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Dated: April 7, 2021

cc: Counsel of Record for Hetero Defendants– via Electronic Mail

Dear Judge Noreika:

Plaintiff Gilead brings this dispute as a result of Defendants Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA, Inc.'s (collectively, "Hetero") complete failure to engage in fact discovery. While Hetero is one of nine defendants in this Hatch-Waxman case, it is the only who refuses to engage in discovery. Hetero simply will not respond. It will not respond to emails, it will not respond to requests to meet and confer, and it will go silent for months at a time. This includes failing to: (1) meaningfully respond to Gilead's requests for production, provide ESI search terms, or produce any documents beyond its FDA documents, (2) meaningfully respond to Gilead's interrogatories; and (3) provide complete disclosures under Paragraph 3 of the Delaware Default Standard. For each issue, the pattern is the same: Gilead repeatedly seeks discovery from Hetero, and Hetero either does not respond or promises to provide updated responses, only for months of silence to pass. Gilead has endeavored at every turn to resolve these disputes without the Court's intervention and was reticent to move to compel on such a large number of issues. Normally, Gilead would hope to significantly narrow, or eliminate, these types of disputes through the meet and confer process but for months, Hetero has refused to do even that, and its eleventh-hour agreement to stipulate does not absolve it of the obligations not mooted by its stipulation. Gilead is left with no other recourse except to seek the Court's intervention at this stage. Simply put, Hetero's improper and nonresponsive tactics can go on no longer.

**Hetero has failed to engage in document discovery beyond the mandatory production of its FDA documents:** Gilead served its first set of RFPs on March 9, 2020. On June 22, Hetero responded, refusing to produce documents for 64 of Gilead's 76 RFPs. For 26 of them, Hetero outright refused to produce any documents. For 38 others, Hetero indicated that it would not produce documents beyond its FDA documents. (*See, e.g.*, Ex. A at 11 ("Hetero has already produced ANDA No[s]. 214179 [and 211850]")).

Gilead contacted Hetero about these deficiencies (Ex. B), and four weeks later Hetero agreed to meet and confer. During the October 13 meet and confer, Hetero agreed to clarify in writing if it would produce documents beyond those that it agreed to produce in its responses to Gilead's RFPs. (Ex. C at 1-2.) Despite three separate requests for Hetero's agreed response, Gilead is still waiting for the promised clarification. (*See* Ex. D at 1-2.)<sup>1</sup> As of today, almost six months after the meet and confer, Hetero still has not provided any production beyond its mandatory FDA documents in response to 64 RFPs.

At a high level, the RFPs that Gilead moves to compel on include:

- "All Documents and Things Concerning this litigation" and documents identified in Hetero's disclosures (**RFPs 1, 3**)
- Documents related to the Asserted Patents (**RFPs 2, 6-7, & 12-13**)
- Patents owned or licensed by Hetero related to TAF (**RFPs 65-66**);

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<sup>1</sup> Prior to filing this motion, Gilead offered at least six times to meet and confer with Hetero without receiving a response. (Ex. E at 2-4, 7-9; Ex. F at 1-2; Ex. G at 2.) Some but not all of these requests have been obviated by Hetero's last minute agreement to stipulate to infringement.

- The market for HIV drugs, Hetero's projected sales/forecasts for its TAF ANDA products, marketing materials, and timeline for FDA approval (**RFPs 18-23, 26-29**);
- Hetero's testing, development, manufacturing, and distribution of its TAF ANDA products, and the business reasons (including relevant meeting minutes) for pursuing them (**RFPs 24-25, 32-35, 40-41, 43, 45-47, 49, 56-59**);
- Research regarding TAF, Gilead's products, and efforts to design around the Asserted Patents (**RFPs 50-55, 60**);
- Hetero's internal structure including consultants retained and document retention policies (**RFPs 67-68, 70, 75**);
- Communications between Hetero and (1) other Defendants about the parties' respective products or the Asserted Patents (**RFPs 71-72**) and (2) prospective customers, agreements, or contracts regarding Hetero's TAF ANDA products (**RFPs 73-74**).

(See Ex. A.) As discussed in more detail below, on the eve of submitting this letter, Hetero agreed to stipulate to infringement. The parties had discussed this simple and straightforward stipulation for months, and Hetero's timing is suspect to say the least. But stipulating to infringement does not dispose of all disputes with respect to Hetero nor absolve it of its discovery obligations. All of the RFPs listed above still seek relevant, proportional information that directly bears on the remaining issues in this litigation. While Hetero has refused to meaningfully meet and confer on these issues, Hetero's position seems to be that it needs to produce its ANDAs and related correspondence with FDA, and no more. But that position has been soundly rejected in Hatch-Waxman cases. See, e.g., *iCeutica Pty Ltd. v. Novitium Pharma LLC*, C.A. No. 18-599, Feb. 13, 2019 Oral Order; see also *Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382, 1387-88 (Fed. Cir. 2014). Notably, every other defendant in this case has agreed to respond to the vast majority of these RFPs. Given their relevance and the lack of any valid reason not to respond fully, Gilead requests the Court compel Hetero to produce documents in response to the full scope of RFPs 1-3, 6-7, 12-13, 18-19, 20-29, 32-35, 40-41, 43, 45-47, 49-60, 65-68, and 70-75 no later than April 23.

Consistent with its apparent view that it need only produce its ANDAs, Hetero has also failed to produce any documents other than its regulatory documents. Only one month remains before the deadline for substantial completion of document production. Gilead has asked Hetero on at least three separate occasions when Hetero intends to begin its document production and Hetero simply has not responded. (See Ex. H.)

Indeed, Hetero has not even provided its ESI search terms. In October 2020, the parties agreed, consistent with the Default Standard, to provide search terms for electronic documents. See D.I. 129, ¶(IV)(b). Having received nothing from Hetero for nearly three months, on December 29, Gilead requested Hetero's search terms. (See Ex. F at 4.) Hetero ignored this request. On January 11, Gilead again emailed Hetero about its search terms. (*Id.* at 3-4.) Again, no response. On January 26, Gilead again contacted Hetero and asked to meet and confer. (*Id.* at 3.) Hetero responded only to say it was "finalizing [its] search terms" and would "get back to [Gilead] next week." (*Id.* at 2-3.) Hetero never provided search terms nor responded to Gilead's follow-up emails of February 11 and March 22. (*Id.* at 1-2.) Six months and as many emails later, despite its statements to the contrary, last night Hetero stated for the first time that it will not use search terms to identify responsive documents. Hetero has not provided

any explanation for how it can collect the responsive documents sought by Gilead's RFPs without the use of search terms.

**Hetero's responses to Gilead's interrogatories also suggest Hetero believes it needs to do no more than produce its ANDAs to satisfy its discovery obligations.** On July 2, 2020, Gilead served Interrogatories seeking information regarding, *inter alia*, the factual and legal bases for filing its ANDAs (**Rog 1**); the development of Defendants' TAF ANDA products (**Rog 2**); and the expected revenues following market launch (**Rog 10**). (See Ex. I at 9-12, 23-24.) Each of these Interrogatories seeks relevant and proportional information. In response to Interrogatories 1 and 2, Hetero only cited its initial disclosures and, pursuant to Rule 33(d), the *entirety* of its ANDAs, which encompass over 65,000 pages. (Ex. B at 1-2.) As Gilead explained to Hetero on the October 13 meet and confer, these responses are deficient both because Hetero's ANDAs do not fully answer the questions posed and because they fail to comply with Rule 33(d). See Fed. R. Civ. P. 33(d)(1); see also *West v. Ultimate Metals Co.*, 2014 WL 466795, at \*2 (N.D. Cal. Feb. 3, 2014). In response to Rog 10, Hetero refused to produce any documents based on relevance. Hetero initially agreed to supplement each of these Interrogatories, and Gilead requested a response by October 30. (Ex. C at 1-2.) But, in an all too familiar pattern, Hetero did not supplement, and despite three additional emails seeking the promised responses, Hetero did not answer. (See Ex. D at 1-2.) Given the above, Gilead respectfully requests the Court order Hetero to supplement its responses Interrogatories 1-2 and 10 no later than April 23.

**Hetero's Paragraph 3 Disclosures:** Hetero's Paragraph 3 disclosures, pursuant to the Delaware Default Standard, only provide four document custodians instead of the required ten. (Ex. J at 2-4.) Additionally, Hetero listed [REDACTED] (*Id.* at 4.) However, on the parties' October 13 meet and confer, Hetero stated there was [REDACTED] and agreed to supplement its disclosures. (Ex. C at 1.) But Hetero has yet to supplement its disclosures, either to include the requisite number custodians or [REDACTED]. Hetero later reversed its prior position, now stating [REDACTED] (Ex. G at 6.) Hetero has not provided an explanation as to why its position now is different, and has still failed to provide the requisite number of custodians. Gilead respectfully requests the court compel Hetero to supplement its disclosures by April 24.

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The only explanation Hetero has offered for its failure to participate in discovery is that *Hetero itself* proposed that it stipulate to infringement. However, Hetero ceased participating in negotiations regarding that stipulation for months. (See Ex. G at 3.) Even when Gilead informed Hetero it had no choice but to bring these disputes before the Court, Hetero remained silent. That is, until the night before Gilead submitted this letter. Hetero's conduct throughout is far afield from what would be expected and proper in this District, and the timing of its response to the stipulation smacks of gamesmanship. Even though the parties were able to finalize and submit the stipulation, it still only moots a small portion of Hetero's discovery obligations. Because Hetero continues to shirk its discovery obligations, Gilead has no choice but to respectfully request the Court compel Hetero's compliance as described herein.

Respectfully submitted,

*/s/ Grayson P. Sundermeir*

Grayson P. Sundermeir (No. 6517)

cc: Counsel of Record for Hetero Defendants – via Electronic Mail